

657—13.10(126,155A) Microbial contamination risk levels. Preparations shall be assigned an appropriate risk level—low, medium or high—according to the corresponding probability of contaminating a preparation with microbial contamination such as microbial organisms, spores, and endotoxins, and chemical and physical contamination such as foreign chemicals and physical matter. The characteristics described in rules 657—13.11(155A), 657—13.12(155A), and 657—13.13(155A) are intended as guides to the diligence required in compounding at each risk level.

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